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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

VS.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal of the State of California First Appellate District

BRIEF IN RESPONSE TO BRIEF FOR THE UNITED STATES AS AMICUS CURIAE AND SUPPLEMENTAL BRIEF

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This brief is filed in response to the brief filed by the United States as amicus curiae on February 23, 1979 (hereafter "amicus brief"), and to call to the Court's attention, pursuant to Rule 16(5), the case of *Friedman v. Rogers,* ..... U.S. ....., 47 U.S. Law Week 4151 (decided February 21, 1979).

ARGUMENT

I.

RESPONSE TO BRIEF OF THE UNITED STATES AS AMICUS CURIAE ON THE ISSUE OF PREEMPTION.

In appellees' Motion to Dismiss or Affirm (hereafter "appellees Motion"), we urged the Court not to consider the preemption issue raised by appellants because the precise question of whether California Health and Safety Code section 26463(m) is preempted by the federal Food, Drug and Cosmetic Act (21 U.S.C. § 360K(a)), and if it is preempted, whether it should be exempt from preemption (21 U.S.C. § 360K(b)), is currently pending before the United States Food and Drug Administration (hereafter "FDA"). (Appellees' Motion, pp. 12-18). We noted that in section 360K of Title 21, Congress established the standards for preemption under the Food, Drug and Cosmetic Act, but expressly delegated the responsibility for determining whether state laws should be preempted to the FDA. *(Ibid).*

In the amicus curiae brief filed by the United States, however, the Solicitor General argues that Health and Safety Code section 26463(m) may be preempted. (Amicus Brief, p. 6). Appellees submit that this contention is erroneous.

As we explained in our Motion to Dismiss or Affirm (pp. 20-30), there is nothing inconsistent between California's prohibition of medical claims for hearing aids and the cautionary warnings required by the Food, Drug and Cosmetic Act. (21 U.S.C. § 352r). In the absence of a clear inconsistency making it impossible to comply with both

state and federal laws, the state law should not be preempted. *Jones v. Rath Packing Co.*, 430 U.S. 519, 540 (1977).

More importantly, the views expressed in the amicus brief contradict the position expressed by the Food and Drug Administration on July 26, 1978 in its proposed regulation exempting section 26463(m) from preemption. (43 Fed.Reg. 33182). The FDA's comments to the proposed regulation state:

> "The Commissioner is also proposing to exempt from preemption California's Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act." (*Ibid*).

Appellees submit that the opinion expressed by the FDA in its proposed regulation is the correct view of this issue.

II.

APPLICABILITY OF FRIEDMAN v. ROGERS.

On February 21, 1979, this Court held in *Friedman v. Rogers*, ... U.S. ....., 47 U.S. Law Week 4151, that a Texas statute prohibiting the practice of optometry under a trade name did not violate the First Amendment. The Court found that where there was "a significant possibility that trade names will be used to mislead the public" (.....

U.S. at ....., 47 U.S. Law Week at 4154), Texas' interest in protecting the public health of its residents justified the restrictions placed on the "commercial free speech" of optometrists.

Appellees submit that *Friedman v. Rogers* is directly applicable to the instant case, in the following respects:

(1) It reaffirms the Court's refusal to apply the "overbreadth" doctrine to commercial speech. (..... U.S. at ....., 47 U.S. Law Week at 4154).

(2) It affirms the opinion previously expressed by Mr. Justice Stewart that the "prior restraint" doctrine is inapplicable to commercial speech. (..... U.S. at ....., 47 U.S. Law Week at 4154).

(3) It holds that the states' power to regulate commercial speech in the interest of public health is not limited to speech that can be proven to be false or misleading, but extends to speech that has a significant possibility of misleading the public. This is precisely the California Legislature's intention in enacting Health and Safety Code section 26463(m). (*See,* Appellees' Motion, p. 34).

(4) As in *Friedman v. Rogers,* there is extensive documentation in the instant case of the grave problems addressed by the state regulatory scheme. (*See,* United States Department of Health, Education and Welfare, *A Report on Hearing Aid Health Care* (C.T. 125-194); *see also,* comments of the Food and Drug Administration, 42 Fed.Reg. 9286, February 15, 1977, and the sources cited therein; Federal Trade Commission, Bureau of Consumer Protection, *Hearing Aid Industry Staff Report* (September,

1978), summarizing and analyzing the evidence in FTC rulemaking proceeding (16 C.F.R. Part 440; 40 Fed.Reg. 26646, June 24, 1975). (43 Fed.Reg. 54103, November 20, 1978)).

Thus, *Friedman v. Rogers* confirms the constitutional validity of California Health and Safety Code section 26463(m).

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